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AGILENT TECHNOLOGIES INC.
INTELLECTUAL PROPERTY ADMINISTRATION, M/S DU404
P.O. BOX 7599
LOVELAND, CO 80537-0599

EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,331

Applicant(s)

PECK ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 17-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 9/25/2006 is acknowledged and has been entered. All of the arguments have been thoroughly reviewed and considered but are deemed moot in view of the new grounds of rejection noted below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

3. The claim objection and claim rejection under 35 USC 112 second paragraph is withdrawn in view of Applicant's amendment of the claims. The prior art rejections under 35 USC 102 and 103 are withdrawn in view of the new grounds of rejection noted below.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-9 and 11-165 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (U.S. Patent No. 5,186,824, issued 16 February 1993).

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Regarding claims 1 and 2, Anderson et al disclose a method of producing an array of at least two different polymeric ligands (e.g. oligonucleotides synthesized on a solid support (e.g. particle, membrane, disc Column 6, lines 49-56) the two different sequences being e.g. product and failed sequences, Column 20, lines 10-25).

Anderson et al disclose the method comprising contacting a blocked monomer at first and second locations having functional groups (e.g. cpg supports having the first monomer attached, Column 19, lines 55-58) under conditions sufficient for the monomer to covalently bond to the surface. Anderson et al further teach detritylation of the nucleotide with a blocking fluid; namely, step i of Table I (column 20), which generates an unblocked attached nucleoside nucleotide. Anderson et al further teach displacing the deblocking fluid with a purging fluid; namely, the solid supports are exposed to reagents sequentially wherein the reagents are kept separate based on density (column 5, lines 3-38 and column 6, lines 13-36) forming a liquid-liquid interface such that the solid support is not exposed to a triple phase interface (column 12, lines 28-67 and Fig. 2A-2D). Anderson et al also teach the reacting of the unblocked attached nucleotide with another blocked nucleoside monomer; namely, coupling step ii of Table I (column 20); removing blocking groups to generate a function group and reiterating the steps to produce the array of at least two ligands (Column 19, line 55-Column 20, line 50). Anderson et al further teach the method wherein the solid supports are exposed to reagents sequentially wherein the reagents are kept separate based on density (Column 5, lines 3-38 and Column 6, lines 13-36) forming a liquid-liquid interface such that the solid support is not exposed to a triple phase interface (Column 12, lines 28-67 and Fig. 2A-2D).

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While the reference does not use the term “array”, the term is defined by dictionary.reference.com as “a larger group, number or quantity of people or things”. Anderson et al teach production of a plurality of oligonucleotides attached to cpg substrate (“1. Oligonucleotide Synthesis”, Columns 19-22 and Column 24, lines 5-35). Therefore, the reference teaches production of an array as claimed.

Regarding Claims 2 and 3, Anderson et al disclose the method wherein the sequentially applied liquids have a different density greater than zero (i.e. increasing density, Column 6, line 57-Column 7, line 14).

Regarding Claims 4 and 8, Anderson et al wherein the washing fluid has a density that is lower than the density of the deblocking fluid (Column 5, lines 3-38 and Column 6, lines 13-36). In one embodiment, Anderson et al teach the deblocking (detritylation) fluid has a density that is greater than that of methylene chloride (i.e., 1.325 g/mL; column 21, lines 1-10). Detritylation is followed with a wash using acetonitrile, which has a density of 0.714 g/mL (Table II, step 3). Calculating the density difference using pure methyl chloride results in an Atwood number of 0.2996; a higher density deblocking fluid gives a higher Atwood number.

Regarding Claim 5, Anderson et al disclose wherein the wash is a low viscosity (see col. 7, lines 68 to col. 8, line 1 and Table II, step 3 with discloses that the wash solution is acetonitrile).

Regarding claim 6, Anderson et al discloses wherein the wash fluid is acetonitrile (column 13, line 67-column 14, line 1), which has a low viscosity (col. 7, line 68 to col. 8, line 1). It is commonly known in the art base standard physical data that acetonitrile has a viscosity

of 0.38 cp. Therefore, it is an inherent property that the wash fluid (acetonitrile) has a viscosity that does not exceed about 1.2 cP.

Regarding Claim 7, Anderson et al disclose wherein said wash fluid is an organic fluid (Table II, step 3).

Regarding Claim 9, Anderson et al disclose the method wherein displacing comprises flowing the subsequent liquid across the surface to produce a stratified liquid interface that moves across the surface (Column 12, lines 28-67 and Fig. 2A-2D).

Regarding Claim 11, Anderson et al teach wherein the method comprises a sensing movement (rotation) that moves a stratified interface across the surface (column 12, lines 28-67 and Fig. 2A-2D).

Regarding Claim 12-14, Anderson et al disclose the method wherein the steps are preformed in a flow cell i.e. internal space for fluid flow so as to contact solid support (Column 5, lines 20-38).

Regarding Claim 15, Anderson et al disclose the method wherein said surface is contacted with a capping liquid prior to said deblocking (Column 13, line 59-Column 14, line 11 and Column 19, line 55-Column 20, line 50). Therefore, Anderson et al meets the limitation of the claims noted above.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 5,186,824, issued 16 February 1993).

Regarding Claim 10, Anderson et al disclose a method of producing an array of at least two different polymeric ligands (e.g. oligonucleotides synthesized on control pore glass, the two different sequences being e.g. product and failed sequences, Column 20, lines 10-25) as previously discussed above.

Anderson et al further teach the method wherein the steps are performed in a flow cell wherein the flow rate is controlled and monitored during passage of reagents (Column 5, lines 25-27; Column 14, lines 44-53 21). Anderson et al teach that it is important to control the flow rate because some synthesis steps take more or less time than other steps and because reagent waste resulting from excess use of reagents is expensive (Column 21, lines 30-65) but they are silent regarding specific flow rates. However, the reference clearly suggests that the flow rate is adjusted to maximize reagents and synthetic step.

Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the flow rate during the synthesis steps of Anderson to obtain optimal flow rates (e.g. about 1-20 cm/x). One of ordinary skill in the art would have been motivated to adjust the flow rate so as to maximize syntheses reaction with minimal waste of reagents as desired by Anderson et al (Column 21, lines 30-65).

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8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 5,186,824, issued 16 February 1993) in view of Blanchard (U.S. Patent No. 6,384,210, issued 7 May 2002).

Regarding Claim 16, Anderson et al disclose the method comprising contacting a blocked monomer at first and second locations having functional groups (e.g. supports having the first monomer attached, Column 19, lines 55-58) under conditions sufficient for the monomer to covalently bond to the surface as previously discussed above.

Anderson et al do not teach monomers addition using a pulse-jet.

However, pulse-jet addition of monomers during multi-step synthesis of polymers was well known in the art at the time the claimed invention was made as taught by Blanchard.

Blanchard teaches a similar method of oligonucleotide synthesis on a solid support wherein the support is placed in a flow cell for all reaction except for monomer addition (Column 4, lines 3-22). Blanchard teach the monomer addition using a pulse jet provides precise, discrete and small volumes of monomer are added to a support (Column 5, lines 41-56) whereby multiple and different monomers dispensed simultaneously thereby greatly reducing the time of array synthesis (Column 11, lines 48-61).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the pulse-jet dispenser of Blanchard to the monomer addition step of Anderson et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of simultaneously providing multiple and different monomers precisely at, discrete and small locations on to the support (e.g. membrane/disc) of Anderson et al with

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greatly reduced time of array synthesis as taught by Blanchard (Column 5, lines 41-56 and Column 11, lines 48-61).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-59 of copending Application No. 10/813,467. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

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Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods for producing polymers on a substrate wherein the polymers are oligonucleotide and nucleotides. The claim sets differ in that the instant claims are drawn to displacing deblocking fluid with a wash fluid, while the '467 defines the same step as "displacing with a purging fluid". Thus, the claims 1-16 of the instant invention falls entirely within the scope of the claims 28-59 of US patent '467. The claims disclose similar methods and are not patentably distinct.

As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), "a second application-- "containing a broader claim, more generic in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. *Miller*, 151, U.S. at 198; See *Stanley*, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., *Titanium metal corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generic application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 11/234,701. An obviousness-type double patenting rejection is appropriate where the conflicting

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claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods for producing polymers on a substrate wherein said polymers are nucleic acid molecule and nucleosides. The claim sets differ in that the instant claims are drawn to displacing fluid with a wash fluid, while the '701 defines the same step as displacing. Therefore, the claim sets are drawn to very similar methods that are not patentably distinct.

As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), "a second application--"containing a broader claim, more generic in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. *Miller*, 151, U.S. at 198; See *Stanley*, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., *Titanium metal corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generic application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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12. Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/813,337. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods for producing polymers on a substrate and differ only that the claims of the '337 are drawn to the generic polymers i.e. ligands and monomers while the instant claims are drawn to a species i.e. nucleic acid and nucleosides. However, the courts have stated that a genus is obvious in view of the teaching of a species see *Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the '337 claimed ligands (i.e. genus) are obvious in view of the instant claimed nucleic acid. The claim sets further differ in that the instant claims are drawn to displacing fluid with a wash fluid, while the '337 defines the same step as displacing without a triple phase interphase. Therefore, the claim sets are drawn to very similar methods that are not patentably distinct.

As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), "a second application-- "containing a broader claim, more generical in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. *Miller*, 151, U.S. at 198; See *Stanley*, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., *Titanium metal corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 11/082,006. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods for producing polymers on a substrate and differ only that the instant claims are drawn to nucleic acid and oligonucleotides while the '006 claims are drawn to a species i.e. nucleic acids and peptides (Claims 12-18). However, the courts have stated that a genus is obvious in view of the teaching of a species see *Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed nucleic acids are obvious in view of the '467 nucleic acid and peptides. The claim sets further differ in that the instant independent claims are drawn to displacing fluid with a wash fluid, while dependent claim 9 of the '006 method defines the fluid movement as spatially controlled. Therefore, the claim sets are drawn to very similar methods that are not patentably distinct.

As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), "a second application-- "containing a broader claim, more generic in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. *Miller*, 151, U.S. at 198; See *Stanley*, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., *Titanium metal corp. v. Banner*, 778 F.2d 775, 227

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USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cynthia B. Wilder, Ph.D.

Patent Examiner

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12/11/2006